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56 List of documents cited in the preliminary search report:
Refer to the end of this document

60 References to other related national documents:

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54 **ADAPTIVE INTRAOCULAR IMPLANT**

57 The adaptive intraocular implant comprises a lens with a central optical part and a peripheral part for holding it in the capsular sac. The peripheral part is one elastically deformable annular piece (1) in the form of a groove open toward the inside with a rear wing (3) in contact with the rear wall and a front wing (2) in contact with the peripheral part resting on the front wall of the capsular sac, the front wing (2) having at least two gabs (4 and 5) in the form of hooks projecting radially from the edge of the wing. The optical part as such is a lens (6) in the form of a disk comprising at least two openings (7 and 8) in its peripheral zone by means of which it is held by the hooks (4, 5) of the annular piece (1).

Used in ophthalmology.

[drawing]

FR 2 784 575 A1

The present invention concerns an intraocular implant intended to be implanted in the location and in place of the natural lens following a cataract operation.

The adaptation is the process by which the eye focuses on approaching objects by means of a controlled deformation and an increase in the curve of the surfaces of the lens. The adaptation mechanism derives from the contraction of the ciliary muscle that relaxes the tensions of the zonule and makes it possible for the lens to assume a rounder shape. In contrast, when the eye focuses on an infinite point, the ciliary muscle is relaxed, the zonule is tensed and the lens is under maximum strain, thus assuming a flatter shape. All individuals lose their ability to adapt, generally during their fifties, and have to wear corrective glasses for reading or for close work, this being called presbyopia.

Presbyopia is due to several factors, in particular to the change in all of the components of the adaptive mechanism: hardening of the material forming the lens, which means that this lens is less deformable and a change in its geometry produced by the continuous growing of the lens. These changes make up a large part of the reduction of the adaptation with age and the appearance of presbyopia.

The opacification of the lens is called cataract; this leads to the loss of vision. The most common cause of the cataract is age. The cataract operation with implantation of an intraocular polymer lens is the most common surgical procedure. The opaque lens is withdrawn through a circular, central opening in the anterior capsule, called capsulotomy. The opening is usually from five to six millimeters in diameter and starts at about two millimeters

from the anterior insertion of the zonule. Phacoemulsification is the procedure by which ultrasound is used to fragment the lens material, which is then withdrawn by aspiration. A synthetic polymethlymethacrylate (PMMA) lens or supple and pliable acrylic polymer lens or silicone-based lens is then inserted on the inside of the capsular sac. The refractive power of the intraocular lens is generally chosen to minimize the post-operative refractive deficiency of the patient, but the ability of the lens to focus is fixed, which does not make it possible to obtain an adaptation.

Numerous tests have been carried out to restore, at least partially, the adaptation ability with an intraocular lens. For this reason, the document US 5 607 472 proposes a lens in at least two parts, a first rear part providing the majority of the refractive power to the lens holding, in front of it, a second deformable part that is connected at the center of the first part and which is connected on the circumference to the edge of the capsulotomy. In addition to the fact that this lens is complicated, the connection of the second part at the edge of the opening on the anterior wall of the capsular sac is far from being practiced successfully.

The German company MORCHER has proposed an intraocular lens that is implanted in the capsular sac. This lens comprises a central optical part of around five and one-half millimeters surrounded by a fine skirt extending toward the back of the optical part with the orifices, this skirt being bordered by a circular reinforcement ring with recesses. The total diameter of this implant is ten millimeters. This implant rests against the internal peripheral part of the anterior capsule. Thus, when the zonule exercises tension on the circumference of the capsular sac, by means of the auxiliary muscle, the lens is displaced

toward the back, which changes the refraction of the eye. Clinical evaluation of this technique has shown that the modifications in refractive power of the eye are limited. In addition to this limited adaptive possibility, the implantation procedure requires an incision longer than that needed to implant pliable, non-adaptive lenses.

To remedy the disadvantage of the existing adaptive lenses, which essentially rest in the fact that it is necessary to make a large incision in the cornea in order to be able to introduce such a lens, of which the exterior diameter is often close to ten millimeters, the present invention uses a lens with two parts, i.e., a capsular tension device that supports an optical part, each of them being introduced in succession into the capsular sac.

More specifically, the object of the invention is an adaptive intraocular implant comprising a lens with a central optical part and a peripheral part for holding same in the capsular sac and for transmission to the optical part the forces and displacements of the equatorial part of the capsular sac, resulting from the change in state of the ciliary muscle. According to the invention, the peripheral part is an annular piece in the shape of a groove open toward the interior with a rear wing in contact with the rear wall and a front wing in contact with the remaining peripheral part of the anterior wall of the capsular sac, the anterior wing having at least two tabs in the form of hooks that project radially from the edge of the wing. The optical part itself is a piece in the shape of a disk having at least two openings in its peripheral zone, by means of which it is mounted on the annular piece.

The annular piece, which in normal state has a large diameter, can be folded into a small space

The optical part is then an implant with very reduced diameter (on the order of seven millimeters) which can also be introduced, folded, across this small corneal incision.

In a preferred embodiment of the invention, the anterior wing of the annular part has, in the area of its root, an annular zone with increased flexibility. This zone can be realized by thinning of the wall of the wing at this location. It is understood that, in this way, the optical part is mounted on a wing that is easily mobile in the manner of a lever that transforms deformations of the equatorial part of the capsular sac, due to forces it is subjected to by the zonule, into displacements. They then play the role of a lever which, when the capsular sac is subjected to a tension in the zonule (distance vision), pushes the central optical piece toward the rear, thus modifying the refractive power of the eye in the sense of a decrease making it possible to focus on infinity. In summary, when the ciliary muscle is contracted, i.e., when the zonule is relaxed, the equatorial part of the capsular sac tends to decrease in diameter due to its own elasticity, which forces the groove to open, and in particular forces the front wing to raise up toward the cornea, thus pulling toward the front of the eye the optical part of the lens, in the sense of an increase in the refractive power of the system. Thus it is a case of adaptation to focus on nearby objects.

Other characteristics and advantages of the invention will be seen from the description of one of these embodiments given below by way of non-limiting examples.

Reference will be made to the attached drawings, in which:

so that it can be introduced through a corneal incision of limited length.

- figure 1 is a cross section view of an implant according to the invention,

- figure 2 is an external perspective view of the optical part of the implant,

- figure 3 is a perspective view of the exterior annular piece of the implant forming the tension device for the capsular sac,

- figures 4 and 5 illustrate, in partial cross section, the two states of the implant at the time of close vision (figure 4) and at the time of distance vision (figure 5).

The implant according to the invention shown in figures 1 to 3 comprises two pieces. A first exterior annular piece 1, of which the cross section is in the shape of a groove open towards the interior, which has an anterior wing 2 and a posterior wing 3. The anterior wing 2 has two tabs 4 and 5—in the case of this figure, diametrically opposed—which project toward the interior of the edge of this wing and which are shaped as hooks on the interior of the volume of the groove. These hooks 4 and 5 are intended to retain the optical part of the implant. This optical part is formed by a piece 6 in the form of a disk—in this case biconvex—separated from the annular piece 1. This piece 6 has two holes 7 and 8 crossing through it, in which holes the hooks 4 and 5 can freely be lodged. It can be noted in this regard that the interior shape of the hooks is such that it prevents practically any movement of the optical disk with respect to the hooks along the optical axis in such a way that a displacement of the hooks of which a component extends parallel to this axis involves a corresponding displacement of the optical disk. In the case shown, the interior shape of hooks 4 and 6 is angular to form stops on the part of the disk outside holes 7 and 8 that is lodged on the inside of the hook. It can be seen that the external diameter of piece 6, on the order of seven millimeters, is greater than

the diameter of the edge of the wings 2 and 3, in such a way that when piece 6 is lodged on the inside of the groove, it can not escape spontaneously. The diameters of the edges of the wings 2 and 3 are not equal, the larger diameter being that of the edge of anterior wing 2.

The base of groove 1—i.e., the part that connects the two wings and which has the maximum external diameter (of nine and one-half millimeters to ten millimeters, a diameter that corresponds to the equatorial diameter of the capsular sac of a person in their thirties)—is thicker than that which makes up the wings 2 and 3. The choice of this dimension (9.5-10 mm) makes it possible to take into account the fact that, at the time of the operation, since the patient is generally at least 60 years old, the crystalline lens has a greater volume in comparison to that which it had when the patient was younger. Replacement in the capsular sac of the lens material by the implant of the invention, thus with equatorial diameter smaller than that of the sac at the time of the operation, allows the sac the possibility of retracting partially on the ring. The result of the retraction is based on a decrease in the relaxation of the zonular fibers that the enlargement of the natural lens has caused. As a result, the changes in state of the ciliary muscle are better transmitted to the equatorial part of the capsular sac. In other words, the decrease in this relaxation makes it possible to transmit to the capsule a greater part of the amplitude of the ciliary muscle displacement than that which can be transmitted to the natural capsule that had enlarged.

Placement of the implant according to the invention on the inside of the capsular sac consists of folding up on itself the annular piece 1 in such a way as to reduce the space required in cross section in order to make it possible to introduce it into the capsular sac by way of a corneal incision

of small length. Once the piece 1 is in place in the sac due to its own elasticity, it forms a holding element of this sac to adjust its equatorial diameter to a value close to that which the lens had when the patient was around 30 years old. Fastening the equatorial diameter of the capsular sac to this dimension, i.e., limiting its partial retraction, is to place it in an optimal situation to promote the maximum amplitude of the ciliary muscle movements transmitted to this sac by the zonule, as explained above. To obtain this result, an adequate dimension of piece 1 would be chosen, using a pre-operative measurement of the equatorial diameter of the lens (by a known method, e.g. by ultrasound), from which between 0.5 and 0.75 mm would be subtracted to determine the advantageous external diameter of the piece 1.

Then the optical part 6 is put in place by introducing it into the groove 1 and, by means of a special instrument, by forcing the hooks 4 and 5 to the inside of holes 7 and 8.

Naturally, parts 1 and 6 of the implant are made of a supple and pliable material known in and of itself, such as an acrylic polymer or silicone-based polymer. It can be seen in figures 1 and 3 that the backs 4a and 5a of the hooks 4 and 5 are in the extension of the external surface of the anterior wing 2. These hooks can thus mold perfectly to the rest of the anterior wall of the capsular sac. It can also be noted that the connecting zone of the hooks to the wing 2 is made up of a part with slight thickness which creates a sort of pseudo-articulation of the hooks with respect to the annular piece 1. This zone is located at 10 in figure 1 and at 11 in figures 4 and 5. In the embodiment of figures 4 and 5, the effect of the amplifying lever of the movement of the hooks 4 and 5 has been illustrated

at the time of tension in the zonular fibers 13.

Figure 4 is a partial cross section view of the implant according to the invention placed in the capsular sac 12, in the state of adaptation, i.e., in the form taken due to the effect of the elastic retraction of the equatorial zone of the capsular sac due to the fact that zonule 13 is relaxed (ciliary muscle contracted).

Figure 5 shows the state of the implant according to the invention when the ciliary muscle is relaxed, i.e., the zonule 13 is tensed, this tension having the effect of flattening the equatorial zone of the capsular sac 12, this flattening causing a swiveling toward the interior of the groove of the hooks 4 and 5 around the zone of great flexibility 11. It is understood that in this state, the optical part 6 of the implant is pushed back toward the back of the eye, which has an effect on the global power of the system, in the sense of a decrease, which is the case of adaptation to focusing on infinity.

The invention may take other forms of embodiment. For example, more than two (three or four) hooks for mounting the optical piece in the annular piece could be put in place.

CLAIMS

1. Adaptive intraocular implant comprising a central optical part and a peripheral part for holding same in the capsular sac and for transmission to the optical part of the forces and displacements of the equatorial part of the capsular sac resulting from changes in state of the ciliary muscle, characterized in that the peripheral part is an annular piece (1) that is elastically deformable and in the shape of a groove that is open towards the interior, with a posterior wing (3) in contact with the posterior wall and an anterior wing (2) in contact with the remaining peripheral part of the anterior wall of the capsular sac, and in that the anterior wing (2) comprises at least two tabs (4 and 5) in the form of hooks projecting radially from the edge of the wing, and in that the optical part itself is a lens (6) in the form of a disk comprising at least two openings (7 and 8) in its peripheral zone, by means of which openings it is held by the hooks (4, 5) of the annular piece (1).

2. Intraocular implant according to claim 1, characterized in that the connecting zone (11) of each hook (4, 5) to the anterior wing has increased flexibility.

3. Implant according to claim 1 or claim 2, characterized in that the back (4a, 5a) of each hook (4, 5) is located in the extension of the external face of the anterior wing (2).

4. Implant according to any one of the preceding claims, characterized in that each hook (4, 5) cooperates with the lens without play in the direction of the optical axis of the implant.

5. Implant according to any one of the preceding claims, characterized in that the connecting part (9) of the two wings of the annular piece has a thickness greater than that of the greatest thickness of each of the wings.

6. Implant according to any one of the preceding claims, characterized in that the diameter of the lens (6) is less than the internal equatorial diameter of the annular piece (1) and is greater than the diameter of the edge of each wing (2, 3).

[see original for Figures 1-5]

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PRELIMINARY SEARCH REPORT

established on the basis of the latest claims
submitted before the beginning of the search

National registration no.
FA 563655
FR 9812945

DOCUMENTS CONSIDERED RELEVANT

Category	Citation of the document with indication, if needed, of the relevant parts	Claims involved in the application examined
A	EP 0 337 390 A (CESKOSLOVENKA AKADEMIE) October 18, 1989 * abstract *	1
A	EP 0 732 090 A (D.W. LANGERMAN) September 18, 1996 * abstract *	1
A	FR 2 681 524 A (M.N.A.O.) March 26, 1993 * column 5, line 12 – line 31; figure 4 *	1
A	US 4 892 543 A (D.F. TURLEY) January 9, 1990 * column 3, line 43 – line 57; figures 2, 3 *	1
A	US 5 814 103 A (I. LIPSHITZ ET AL.) September 29, 1998 * column 4, line 30 – line 37; figure 5 *	1
A	US 5 800 533 A (H.C. EGGLESTON ET AL.) September 1, 1998 * abstract *	1
A	US 5 026 396 A (J.J. DARIN) June 25, 1991 * abstract; figures 2, 5 *	1
A	US 5 674 282 A (J.S. CUMMING) October 7, 1997 * column 9, line 33 – line 56; figures 2, 3 *	2

TECHNICAL AREAS RESEARCHED (Int. Cl.6)

A 61F

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CATEGORY OF DOCUMENTS CITED

X: particularly relevant by itself
Y: particularly relevant in combination with another document in the same category
A: pertinent with respect to at least one claim or general technical background
U: unwritten disclosure
P: inserted document

T: theory or principle on which the invention is based
E: patent document having a date prior to the date of application and which had not been published until this date of application or a later date.
D: cited in the application
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